RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects and Animals in Navy Research

Volume 2, Number 4 ***human.research@med.navy.mil*** ***June / July 2007***

Comment

Getting Started—and Beyond

As the DON HRPP builds stronger outreach and education initiatives, it continues to learn of Navy and Marine Corps commands and activities, both in the United States and overseas, that seek to conduct research with human subjects.

The DON HRPP has assembled a "Getting Started" kit for commands without an Institutional Review Board (IRB) that will rely on an IRB at another command.

The "Getting Started" package responds to the needs of commands for the fundamentals of standing up HRPP programs that comply with Navy policy.

Recently, the Surgeon General approved Assurances for three Navy activities that will rely on the IRBs of other commands. The Naval Health Clinic Quantico, Va., and the Fleet Aviation Specialized Operational Training Group Brunswick, Me., both will rely on the National Naval Medical Center IRB. The Naval Special Warfare Group 2 Norfolk, Va., will rely on the IRB at the Naval Medical Center Portsmouth, Va.

The "Getting Started" kit provides the foundation needed for a straightforward program that complies with the latest policy guidance.

The kit provides everything a command planning to rely on another command's IRB needs, beginning with a set of easy-to-follow directions for establishing a Human Research Protection program.

The directions are accompanied by four baseline HRPP documents: (1) the DoD Navy Assurance for DoD Institutions Without an IRB, an application for an Assurance used by commands planning to rely on another command's IRB for review of research; (2) a DoD-Navy Institutional Agreement for IRB Review, which describes the responsibilities of the institution engaged in research with human subjects and those of the DoD institution with the IRB that will review the research.

The other two documents are (3) a Command HRPP template for policies and procedures for initiating, monitoring, overseeing, and completing human subject research; and (4) a template for an easy-to-follow flow chart that illustrates the process for submitting research protocols and the accompanying chain of communications for commands without IRBs.

The most important feature of the "Getting Started" package is that it responds to the needs of commands for the fundamentals of standing up HRPP programs that comply with Navy policy by helping them to get started on the processes for approving research. The package helps commands identify the training and reporting requirements of a full-up HRPP program.

Meanwhile, "Getting Started" also reminds commands that the DON HRPP isn't just a regulatory office—it is, and will continue to be, an essential resource for support for the Navy's critical human subject research.

Also in this Issue:

Professional Development

Human Research Certification–Is It for You?

CIP, CIM, CRA, CRC, CPI, CCRP, and CPI—what do these sets of initials have in common? All represent certification for work in the field of research with human subjects.

Certification represents a standard for experience and professional knowledge that supports awareness of and adherence to ethical principles in human subject research. As with a college degree, though, certification is not an endorsement or a guarantee of an individual's qualifications or performance.

Over the past 20 years, research with human subjects has evolved from investigator-led research protocols conducted at single institutions to collaborative protocols conducted at multiple institutions. In that time, human research protections has become a highly respected professional field.

Oversight of research with human subjects also has become far more complex, and recent scrutiny of human research practices has revealed the need for a far greater degree of individual and institutional accountability than in the past. The certification of individuals, along with the accreditation of institutional programs, is a benchmark for standards for protecting human research subjects.

Who benefits from certification? In addition to a sense of professional achievement, certified human subject research professionals enjoy enhanced career opportunities. Many institutions seek to hire certified persons; others support certification as an aspect of professional development. Certified IRB professionals strengthen an institution's human research protection program by improving IRB administration and regulatory compliance. Most important, research subjects benefit from participating in research at institutions staffed by certified professionals who are well-attuned to subjects' safety and well-being.

Two certification programs have been established for IRB professionals: the Certified IRB Professional (CIP), which is sponsored by the Council for the Certification of IRB Professionals; and the Certified IRB Manager (CIM), sponsored by the National Association of IRB Managers. Both programs have published mission statements and maintain eligibility criteria, a "Body of Knowledge," and testing and recertification requirements.

The CIP test, offered twice annually at over 700 testing sites, challenges candidates' knowledge of four major areas: foundations and concepts of IRB practice, organizational and personnel knowledge, IRB functions and operations, and records and reports. Certification is valid for three years. Currently, some 2 percent of the nearly 900 CIP-certified individuals are either military personnel or Department of Veterans Affairs staff members. For more information see www.ptcny.com .

The CIM test, also offered twice annually, is an "open book" exam offering extra credit questions. Candidates are allowed six weeks to complete the exam, which tests their knowledge on such topics as the responsibilities of a research assistant, legal consent, retrospective chart review, records management, IRB ethics, government compliance, deception, pharmacy administration, and site audit. Certification expires on June 30 three years from the year awarded. About 700 individuals, mostly civilians, hold the CIM credential. See www.naim.org/index.htm for details.

Certification programs aimed at research coordinators, research assistants, and clinical investigators are described below.

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Significant Changes from "C" to "D"

The DON HRPP has compiled a comprehensive table of the key changes in policy that are reflected in the current Navy Human Research Protection Policy, SECNAVINST 3900.39D, which replaces SECNAVINST 3900.39C. The table is accessible on the DON HRPP website at:

http://navymedicine.med.navy.mil/humanresearch/

and will be accessible at the Research Protections Division, Office of Naval Research website at:

http://www.onr.navy.mil/sci_tech/34/343/

DON Animal Research Protection

Contracted Animal Care

By Col. Mark Gold

For intramural animal care and oversight, most facilities rely on the active engagement of their respective Institutional Animal Care and Use Committees to set standards, grant approvals, and follow up with post-approval monitoring.

The DoD has added an extra layer of oversight for research involving dogs, cats, marine mammals, and nonhuman primates to ensure that we stand on the moral high ground in our animal work.

So what standards apply when we contract with others to provide necessary animal care, or fund research at extramural facilities? The use of animals in commercial combat trauma training is just one of the high-profile issues that raise these questions for all potential contracting issues.

SECNAVINST Requirements

SECNAVINST 3900.38C (AR 40-33) states that a DoD veterinarian trained or experienced in laboratory animal medicine or science administratively reviews the proposed work before release of funding. But when are we contracting for animal care or research?

This question arises frequently regarding the right approach to conducting such a review. Even for those performing extramural contracted care and/or research review, it's a tough question.

The answers are easiest when an agency is paying for direct animal care or granting money for animal-use protocols proposed at extramural facilities. Those scenarios clearly meet the definition of contracted animal care / research, and are subject to the requirements for conducting this review delineated in the SECNAVINST. Our office provides review of protocols for work to be contracted by the Office of Naval Research prior to funding of the effort. Veterinarians assigned to our DON research facilities do the same, forwarding their proposals to our office at BUMED or conducting the reviews themselves, in accordance with the SECNAVINST.

Training Scenarios

The answer is more complicated in other cases. Consider the scenario of a young physician or veterinarian attending a class or residency at a civilian facility. He or she probably will attend a "wet lab" or an Advanced Trauma Life Support (ATLS) course sponsored by the American College of Surgeons in their training.

> ***"The DoD has added an extra layer of oversight for research involving dogs, cats, marine mammals, and nonhuman primates to ensure that we stand on the moral high ground in our animal work."***

If the DoD is paying for the wet lab or ATLS course, does that mean that the host is contracting to perform "contracted animal care" for DoD? Because most facilities explicitly follow the Animal Welfare Regulations (9 CFR) and are subject to USDA oversight, in most cases the answer would be no.

In another scenario, a DoD agency may want a university or company to conduct a class on a military base only for DoD personnel, or within parameters required by the agency. The best guidance: check with your Component Veterinarian (BUMED, Veterinary

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Don't Forget Our E-Mail Address Changes!

Our e-mail address has changed. DON HRPP is no longer humanresearch@us.med.navy.mil; now we're human.research@med.navy.mil. Just put a dot between the 'human' and 'research' and take the 'us' out after the '@'. Not big changes, but please make them so we can stay in touch.

E-mail addresses are also changing at the Office of Naval Research. We'll keep you informed as they change.

Human Research Certification–Is It for You?

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The Clinical Research Associate (CRA) monitors the administration and progress of a clinical trial on behalf of a sponsor. Candidates for CRA certification must have a college degree plus relevant work experience. Recertification is required every two years. About 6,100 CRAs have been awarded.

Some 11,700 Clinical Research Coordinators (CRCs) work at clinical research sites under the immediate direction of a principal investigator. To meet eligibility requirements, at a minimum, individuals must have a high school diploma or equivalent, and at least two years experience enrolling subjects, conducting subject study visits, and maintaining source documents. Recertification is required every two years.

One of the newest certification programs is the Clinical Trial Investigator (CTI). A CTI works at clinical research sites as the non-physician investigator whose research is conducted under Good Clinical Practices and Food and Drug Administration regulations. Candidates must be a doctoral level or equivalent clinical research professional, e.g., PhD, PharmD, Doctor of Nursing Science, Nurse Practitioner, or Physician's Assistant, and have two years' experience. Currently 16 persons are certified as CTIs.

The CRA, CRC, and CTI are sponsored by the Association of Clinical Research Professionals (ACRP). See http://www.acrpnet.org/ for more information.

A Clinical Research Professional (CCRP) works as a clinical researcher, research nurse, administrator, coordinator, consultant, or educator in clinical trials research. Membership in the Society of Clinical Research Associates (SoCRA) and a combination of work experience and degree are necessary for a three-year certification. More than 5,100 CCRPs support clinical research. The CCRP is sponsored by SoCRA; see http://www.socra.org/ for details.

The Certified Physician Investigator (CPI) is a physician (M.D. or equivalent degree) who serves as an investigator, supervises or designs clinical trials, and accepts responsibility for the safe and ethical conduct of clinical trials. In addition to the medical degree or equivalent, experience and a license are required for the two-year certification. The Academy of Pharmaceutical Physicians and Investigators (http://aapp.org/file.php?ID=Certification+Info) sponsors the CPI.

Contracted Animal Care

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Affairs: 202-762-0253/0252), your servicing Staff Judge Advocate, or contracting office. The level to which DoD dictates course content, class participants, or even location will affect the answer.

Commercial combat trauma training is a difficult topic. Some medical operators seek classes prior to deployment, and point to the studies and "lessons learned" reports that extol its benefits. A key question is how the classes are provided—buying seats in a class, providing it on a base, etc.

The Vice Chief BUMED recently signed policy (NAVMED Policy 07-007) requiring that all commercial combat trauma training have a veterinary review regardless of how many DON folks attend, method of funding, or location.

The Joint Technical Working Group (Animal Care) of the Armed Services Biomedical Research Evaluation and Management (ASBREM) is drafting a similar DoD policy that should be complete by late summer as a policy letter to augment the SECNAVINST.

We're obliged to help keep the DoD on the moral high ground regarding animal care and use. Let's work together to do our best.

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RESEARCH PROTECTIONS UPDATE *is published monthly by the Department of the Navy Human Research Protection Program. E-mail address: human.research@med.navy.mil. Captain Eileen Villasante, publisher. Edward J. Walsh, editor; Telephone: (703) 588-1010; E-mail: ed.walsh.ctr@navy.mil.*